

MEDICATION GUIDE

PEG-Intron TM **Peginterferon alfa-2b** **Powder for Injection**

Read this Medication Guide carefully before you start taking PEG-Intron (**Peg In-tron**) . Read the Medication Guide each time you refill your prescription because there may be new information. The information in this Medication Guide does not take the place of talking with your doctor.

What is the most important information I should know about PEG-Intron?

PEG-Intron is a treatment for some people who are infected with the hepatitis C virus. However, PEG-Intron, can have serious side effects that may cause death in rare cases. Before starting treatment, you should talk to your doctor about the possible benefits of PEG-Intron, and its possible side effects to decide if PEG-Intron is right for you. While taking PEG-Intron, you will need to see your doctor regularly for medical examinations and lab tests to make sure your treatment is working and to check for side effects.

The most serious possible side effects of PEG-Intron include:

Mental health problems and suicide. PEG-Intron may cause patients to develop mood or behavioral problems. These can include irritability (getting easily upset) and depression (feeling low, feeling bad about yourself, or feeling hopeless). Some patients may have aggressive behavior. Former drug addicts may fall back into drug addiction or overdose. Some patients think about hurting or killing themselves or other people and some have killed (suicide) or hurt themselves or others. You must tell your doctor if you are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal behavior. You should tell your doctor if you have ever been addicted to drugs or alcohol.

Heart problems. Some patients taking PEG-Intron may develop problems with their heart, including low blood pressure, fast heart rate, and very rarely, heart attacks. Tell your doctor if you have had any heart problems in the past.

Blood problems. PEG-Intron commonly lowers two types of blood cells (white blood cells and platelets). In some patients, these blood counts may fall to dangerously low levels. If your blood counts become very low, this could lead to infections or bleeding.

Body organ problems. Certain symptoms like severe stomach pain may mean that your internal organs are being damaged.

While taking PEG-Intron, you should call your doctor immediately if you develop any of these symptoms: new or worsening mental health problems such as thoughts about hurting or killing yourself or others, trouble breathing, chest pain, severe

stomach or lower back pain, bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or decreased vision.

For other possible side effects of PEG-Intron, see “What are the possible side effects of PEG-Intron” in this Medication Guide.

What is PEG-Intron?

PEG-Intron is a drug used to treat adults who have a lasting (chronic) infection with hepatitis C virus but whose liver still works normally. Patients with hepatitis C have the virus in their blood and in their liver. PEG-Intron reduces the amount of virus in the body and in some patients (1 in 4), no virus can be found in the blood after taking PEG-Intron for 1 year. We do not know if PEG-Intron can cure hepatitis C (permanently eliminate the virus) or if it can prevent liver failure or liver cancer that is caused by hepatitis C infection.

There is no reason to believe that PEG-Intron therapy will prevent a person with hepatitis C from giving another person hepatitis C infection.

Who should not take PEG-Intron?

Do not take PEG-Intron if you:

- are pregnant, planning to get pregnant, or breast feeding
- have autoimmune hepatitis (hepatitis caused by your immune system attacking your liver) or unstable liver disease.
- had an allergic reaction to another alpha interferon or are allergic to any of the ingredients in PEG-Intron. (See ingredients listed at the end of this Medication Guide).

If you have any of the following conditions or serious medical problems, discuss them with your doctor before taking PEG-Intron:

- depression or anxiety
- sleep problems
- high blood pressure
- previous heart attack, or other heart problems
- liver problems (other than hepatitis C infection)
- any kind of autoimmune disease (where the body’s immune system attacks the body’s own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- thyroid problems
- diabetes
- colitis (inflammation of the bowels)
- cancer
- hepatitis B infection
- HIV infection (the virus that causes AIDS)
- kidney problems
- bleeding problems

- alcoholism
- drug abuse or addiction
- body organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system).

How should I take PEG-Intron?

Your doctor will decide your prescribed dose of PEG-Intron based on your weight. PEG-Intron is given once a week for one year. Take your prescribed dose of PEG-Intron on the same day of each week and at approximately the same time. Take the medicine for the full year and do not take more than the prescribed dose.

You should be completely comfortable with how to prepare PEG-Intron; how to measure the dose you take; and how to inject yourself before you use PEG-Intron for the first time. Your health care provider will train you in the proper techniques for doing this. See the section “How do I prepare and inject the PEG-Intron dose” below for written instructions.

If you miss a dose of PEG-Intron, take the missed dose as soon as possible during the same day or the next day, then continue on your regular dosing schedule. If several days go by after you miss a dose, check with your doctor about what to do. Do not double the next dose or take more than one dose a week without talking to your doctor. Call your doctor right away if you take more than your prescribed PEG-Intron dose. Your doctor may wish to examine you more closely, and take blood for testing.

You must get regular blood tests to help your doctor check how the treatment is working and to check for side effects.

Tell your doctor if you are taking or planning to take other prescription or non-prescription medicines, including vitamin and mineral supplements and herbal medicines.

What should I avoid while taking PEG-Intron?

- Avoid becoming pregnant while taking PEG-Intron. PEG-Intron may harm your unborn child or cause you to lose your baby (miscarry).
- Do not breastfeed your baby while taking PEG-Intron.

What are the possible side effects of PEG-Intron?

Possible, serious side effects include:

- **Mental health problems including suicide, blood problems, heart problems, body organ problems.** See “What is the most important information I should know about
- **Other body organ problems.** A few patients have lung problems (such as pneumonia or inflammation of the lung tissue), inflammation of the kidney, and eye disorders.

- **New or worsening autoimmune disease.** Some patients taking PEG-Intron develop autoimmune diseases (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, and psoriasis. In some patients who already have an autoimmune disease, the disease worsens on PEG-Intron.

Common but less serious side effects include:

- **Flu-like symptoms.** Most patients who take PEG-Intron have "flu-like" symptoms (headache, muscle aches, tiredness and fever) that usually lessen after the first few weeks of therapy. You can reduce some of these symptoms by injecting your PEG-Intron dose at bedtime. Over-the-counter pain and fever reducers, such as acetaminophen or ibuprofen, can be used to prevent or reduce the fever and headache.
- **Extreme fatigue (tiredness)** Many patients become extremely tired while on PEG-Intron.
- **Appetite problems.** Nausea, loss of appetite, and weight loss, occur commonly.
- **Thyroid problems.** Some patients develop changes in the function of their thyroid. Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot all the time, a change in your weight and changes to your skin.
- **Blood sugar problems** Some patients develop problems with the way their body controls their blood sugar and may develop high blood sugar or diabetes.
- **Skin reactions.** Redness, swelling, and itching are common at the site of injection. If after several days these symptoms do not disappear contact your doctor. You may get a rash during therapy. If this occurs, your doctor may recommend medicine to treat the rash.
- **Hair thinning.** Hair thinning is common during PEG-Intron treatment. Hair loss stops and hair growth returns after therapy is stopped.

These are not all of the side effects of PEG-Intron. Your doctor or pharmacist can give you a more complete list.

How do I prepare and inject the PEG-Intron Dose?

- ◆ Before you inject PEG-Intron, the powder must be mixed with **0.7 mL** of the supplied DILUENT for PEG-Intron, Sterile Water for Injection (diluent). You should carefully follow the directions given to you by your doctor. After you have mixed the diluent and powder, and the solution is completely dissolved, it should be clear, colorless and without particles. Do not use it if you see particles or the color is not correct; call your doctor, nurse, or pharmacist.
- ◆ The vial of mixed PEG-Intron should be used immediately, so **DO NOT** prepare more than one vial at a time.

Preparing the PEG-Intron solution:

1. Check the date printed on the PEG-Intron carton to make sure that the expiration date has not passed.
2. Wash your hands thoroughly with soap and water, rinse and towel dry.
3. The supplies you will need are provided in the PEG-Intron package; you should place them on a clean work area. The PEG-Intron package contains a vial of PEG-Intron powder, a 5-mL vial of DILUENT, 2 disposable syringes, and alcohol swabs. These syringes have a needle already attached that can not be removed and are for single use only.

The disposable syringe provided has a clear plastic safety sleeve that is pulled over the needle after use for disposal. Figure A indicates the safety sleeve as well as the other parts referred to in these instructions. The safety sleeve should be tight against the flange for use and moved over the needle only when ready for disposal, as instructed in step 18.

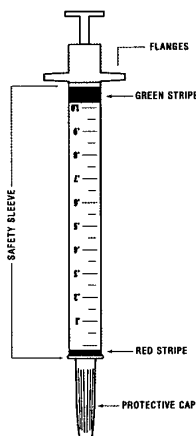


Figure A

4. Remove the protective wrapper from ONE of the syringes provided and use for the following steps 5-7.
5. Remove the protective plastic cap from the tops of both the supplied DILUENT and the PEG-Intron vials. Clean the rubber stopper on the top of both vials with an alcohol swab.
6. Remove the protective cap from the needle and fill the syringe with air by pulling the plunger to 0.7 mL (Figure B). Hold the DILUENT vial upright. Do not touch the cleaned top of the vial with your hands. (Figure C). Insert the needle through the rubber stopper of the DILUENT vial, and inject the air in the syringe into the vial (Figure D). Turn the vial upside down and make sure

the tip of the needle is in the liquid. **Withdraw only 0.7 mL of DILUENT** by pulling the plunger back to exactly 0.7 mL (Figure E). The marks on the side of the syringe indicate the amount of DILUENT to withdraw. Remove the needle from the vial (Figure F). **Discard the remaining DILUENT.**



Figure B

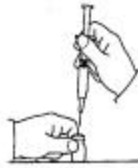


Figure C

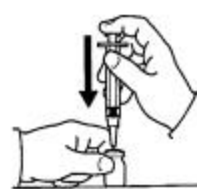


Figure D

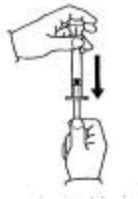


Figure E



Figure F

7. Insert the needle through the rubber stopper of the PEG-Intron vial, and place the needle tip against the glass wall of the vial (Figure G). Slowly inject the 0.7 mL DILUENT, so that it runs down the glass. To prevent producing bubbles, **DO NOT AIM THE STREAM AT THE WHITE POWDER** in the bottom of the vial. Remove the needle from the vial, pull the safety guard over the needle, and dispose as instructed in step 18 below. A new syringe will be used for injection of the medication.

Swirl the vial with a gentle circular motion (Figure H), until the PEG-Intron powder is completely dissolved. If the solution is cold, warm the vial by gently rolling it between your hands. If air bubbles do form, wait until the solution has settled and all bubbles have risen to the top of the solution and disappeared before withdrawing your dose from the vial.



Figure G



Figure H

8. When the PEG-Intron powder is completely dissolved it will be clear, colorless and without particles. Do not use it if you see particles or the color is not correct; call your doctor, nurse, or pharmacist.

9. The solution of PEG-Intron contains no preservatives and should be used immediately.

10. After the PEG-Intron powder is dissolved, clean the vial's rubber stopper with an alcohol swab again.

11. Take the second syringe provided and unwrap it. You will use it to give yourself the injection. Remove the protective cap from the needle and fill the syringe with air by pulling the plunger to the number **(mL)** that corresponds to your prescribed dose (Figure J). Hold the PEG-Intron vial upright. DO NOT touch the cleaned top of the vial with your hands (Figure K). Insert the needle into the vial containing the PEG-Intron solution and inject the air into the vial. (Figure L).



Figure J



Figure K

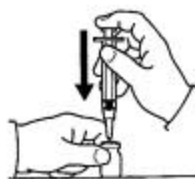


Figure L

12. Turn the PEG-Intron vial upside down. Be sure the tip of needle is in the Peg-Intron solution. While holding the vial and syringe with one hand slowly pull the plunger back to withdraw into the syringe the exact amount of PEG-Intron your doctor told you to use (Figure M).

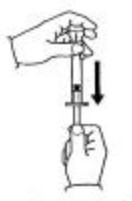


Figure M

13. Remove the needle from the vial (Figure N) and check for air bubbles in the syringe. If you see any bubbles, hold the syringe with the needle pointing up and tap the syringe gently until the bubbles rise. Then push the plunger in slowly until the bubbles disappear.



Figure N

Injecting the PEG-Intron Dose

14. Selecting the Site for Injection.

- The best sites for giving yourself an injection are those areas with a layer of fat between the skin and muscle, like your thigh, the outer surface of your upper arm, and abdomen. Do not inject yourself in the area near your navel or waistline. If you are very thin, you should only use the thigh or outer surface of the arm for injection.
- Do not inject PEG-Intron solution in the same place all the time. You should change your injection site each time in a regular pattern.

15. Clean the skin where the injection is to be given with an alcohol swab, and wait for the area to dry. Remove the protective cap from the needle. Make sure the safety sleeve of the syringe is pushed firmly against the syringe flange so that the needle is fully exposed (see figure A.).

16. With one hand, pinch a 2-inch fold of loose skin. With your other hand, pick up the syringe and hold it like a pencil. Position the bevel of the needle facing up and insert the needle approximately $\frac{1}{4}$ inch into the pinched skin at approximately a 45 to 90 degree angle with a quick dart-like thrust. After the needle is in, remove the hand that you used to pinch your skin and use it to hold the syringe barrel. Pull the plunger of the syringe back very slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do not inject.** Withdraw the needle and discard the syringe as outlined in step 18. Repeat the above steps with a new vial to prepare a new syringe and inject the medicine at a new site. If no blood is present in the syringe, inject the medicine by gently pressing the plunger all the way down the syringe barrel.

17. Hold an alcohol swab near the needle and pull the needle straight out of the skin. Press the alcohol swab over the injection site for several seconds. Do not massage the injection site. If there is bleeding, cover it with a bandage.

18. After use, firmly grasp the safety sleeve and pull over the exposed needle until you hear a click, and the green stripe on the safety sleeve covers the red stripe on the needle (Figure O). Discard the syringe and needle after each use in the Sharp's container supplied to you. The full container should be disposed of according to the directions provided by your doctor or nurse. Do not leave used supplies or the Sharp's container in an open area.

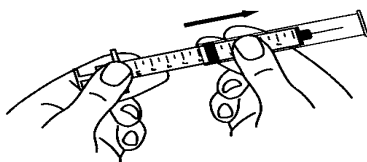
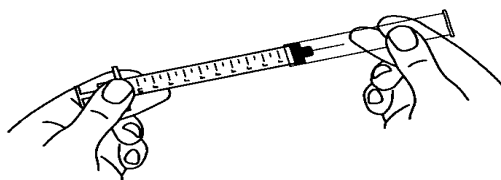


Figure O



19. After 2 hours, check the injection site for redness, swelling, or tenderness. If you have a skin reaction and it doesn't clear up in a few days, contact your doctor or nurse.

Storing PEG-Intron.

PEG-Intron Powder should be stored at room temperature (25 ° C, 77°F); avoid exposure to heat. After mixing, the PEG-Intron solution should be used immediately but may be stored in the refrigerator up to 24 hours. The solution contains no preservatives. Do not freeze.

General advice about prescription medicines:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns about PEG-Intron, ask your doctor. Your doctor or pharmacist can give you information about PEG-Intron that was written for health care professionals. Do not use PEG-Intron for a condition for which it was not prescribed. Do not share this medication with other people.

Ingredients: pegylated interferon alfa-2b, dibasic sodium phosphate, monobasic sodium phosphate, sucrose, and polysorbate 80.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by: Schering Corporation, Kenilworth, NJ 07033 USA

Issued: **DATE**